Cost Management through Care Management, Part 2: The Importance of Managing Specialty Drug Utilization in the Medical Benefit

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In our previous article, we outlined the importance of choosing a specialty pharmacy that is able to implement clinical and utilization management programs to maximize patient outcomes and minimize the waste associated with specialty pharmaceuticals.[1] Those crucial capabilities prevent unnecessary plan expenditures on specialty medications. Each specialty medication covered by a payer is a substantial investment in a patient's healthcare, often costing $20,000 to $200,000 or more annually. Clinical programs help to ensure that investment lessens the patient's disease burden to the fullest extent possible. Utilization management programs ensure the best clinical outcome at the lowest possible cost to treat. The best specialty pharmacies provide competitive unit pricing for drugs, as well as clinical and utilization management programs to their clients.

The primary focus of the previous article was on medications that are typically self-administered by patients and that usually fall under the pharmacy benefit.[1] However, approximately 50% of the specialty drug expense is under the medical benefit.[2] These medications, which are normally infused, are administered by a healthcare provider in various sites of service, most often in the physician's office, in the hospital outpatient department, and in the patient's home (**Figure 1**, page 360). For medical claims, usually the drug and the professional fees related to the drug administration are billed directly to the medical carrier.

The most common specialty drugs covered under the medical benefit (**Figure 2**, page 360) include chemotherapeutic agents (eg, bevacizumab and rituximab) and nonchemotherapeutic agents (eg, infliximab, natalizumab, and immunoglobulin). Chemotherapy support agents (eg, pegfilgrastim, darbepoetin, and epoetin) also represent a significant amount of medically covered specialty pharmacy utilizations. These products are expensive, with some infusions costing more than $200,000 annually.

Unlike most self-administered specialty drugs that are dispensed by specialty pharmacies, drugs covered under the medical benefit are billed directly to the health plan, usually via a CMS 1500 or UB-04 claim form. These claims typically do not undergo the same real-time processing as do pharmacy claims, they can be obscured by "bundle billing" (where multiple services are reimbursed under 1 code), and they are often billed to a payer after the procedure or infusion has occurred. These claims usually are not consolidated with a patient's pharmacy claims; therefore, they often limit a payer's visibility into cost and utilization trends. In addition, depending on the site of administration, and often on the specialty of the physician administering the drug, the cost for a drug covered by the medical benefit can vary widely.

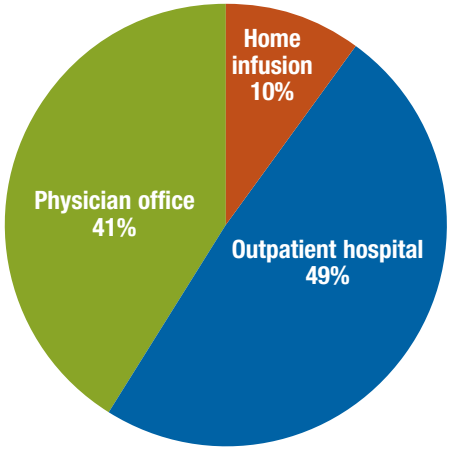
The result is that specialty drugs that are covered under the medical benefit have significant variance in cost, tend to be more difficult to analyze, and do not have the same degree of structured clinical and utilization management programs as their pharmacy-adjudicated counterparts. These dynamics present challenges to the effective management of specialty pharmaceuticals in the medical benefit.

How can payers ensure that medically billed drugs receive the necessary cost, clinical, and utilization management safeguards for these complex long-term therapies? This article outlines key areas within the medical benefit that payers can impact, and the steps they can take to address these opportunities.

Medical Benefit Drug Management

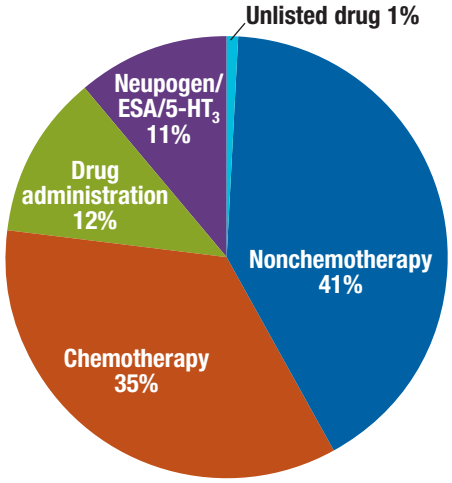
Pharmacy benefit managers (PBMs), such as Express Scripts and CVS Caremark, realize that half of the specialty drug utilization is reimbursed outside of their traditional business models. In response, many PBMs are creating medical benefit management (MBM) programs to help clients understand and manage these drugs. Non-PBM organizations, such as Walgreens, along with various consulting groups, are also developing MBM programs. The spectrum of MBM is very broad, because vendors have developed their programs based on their own interpretations of the medical/specialty opportunity and on

Figure 1 Distribution of Costs for Medically Billed Drugs, by Place of Service



Source: These data are based on client claims from 3 commercial health plans representing 2,436,727 covered lives between January 1, 2011, and December 31, 2011.

Figure 2 Medical Benefit Costs, by Service Type



ESA indicates erythropoietin-stimulating agent.
Source: These data are based on client claims from 3 commercial health plans representing 2,436,727 covered lives between January 1, 2011, and December 31, 2011.

their ability to effectively build a business in this space.

Some MBM programs are focusing on the management of chemotherapy regimens and are lowering the cost of chemotherapy by requiring practicing oncologists and hematologists to follow structured clinical prescribing guidelines, which are known as "oncology pathways." For example, CVS Caremark has stated that a 15% savings on chemotherapy costs can be achieved through its version of oncology pathways.[3]

Other programs are focusing on affecting the distribution channels of specialty drugs, by requiring physician offices to obtain specialty drugs infused in the office from a specialty pharmacy. Other MBM programs offer to manage a health plan's infusible fee schedule in an attempt to standardize the cost of a drug throughout the plan's network and/or recommending a medical drug formulary.

Therefore, MBM means various things to different groups, depending on their area of focus and expertise. This article presents a broad perspective of MBM, with suggestions on key areas where payers should focus their initial efforts to manage drug-related costs within the medical benefit.

PBMs are experts on how pharmacy claims are transacted. Health plans are experts on how medical services are delivered and transacted. These transactions today are isolated into 2 discreet worlds. Although pharmacy data enjoy National Council for Prescription Drug Programs standards, which allows PBMs to build structured claims databases on consistent standards, medical data standards tend to be less consistent. Standards are established on claim forms such as the CMS 1500 (which is used for professionally billed claims, eg, for physician offices) and the UB-04 (which is used for institutionally billed claims, such as for outpatient hospitals), but each plan may require different information on the forms. In addition, the way health plans and data aggregators capture and store the claims information is inconsistent throughout the industry.

To effectively discuss MBM strategies, a thorough understanding of medical claims data is imperative. In our experience, even sophisticated health plans do not have the same level of understanding and reporting capabilities of medically covered specialty drugs that they have of drugs covered through pharmacy-transacted (ie, PBM) claims. Self-insured employers tend to not have access to accurate or thorough medical data through their data aggregator vendors.

Why Not Just Mandate Every Drug Claim Be Covered Exclusively Under the Pharmacy Benefit?

Because medical and pharmacy claims are billed through 2 different systems, some argue that the best solution is to deny medical claims for infusions and to require that the claims be filled under the pharmacy benefit, because it simplifies how the claims are transacted. This solution, however, introduces significant benefit design complexity and changes the underlying pricing dynamic of the claim, both of which must be fully evaluated before adopting such a strategy. Plans with a "carved-out" pharmacy benefit face additional challenges. Significant due diligence is required before proceeding with this approach.

Therefore, when investigating ways to manage medically covered specialty drugs, an employer or a health plan often has to engage a consultant with expertise in analyzing medical data. The consultant should be able to readily produce sample reporting, standard data layouts, and client testimonials that show the ability to discover and understand medical data. This is needed to ensure that all opportunities are uncovered, and to successfully report on the effectiveness of any MBM program, once installed.

You've Collected Accurate Data—Now What?

At Walgreens, we see 4 distinct areas of opportunity to managing medical specialty trend. We believe that an effective MBM program should address all of these 4 areas:

- Site-of-care (SOC) optimization
- Physician office specialty drug distribution
- Clinical and formulary management
- Fee schedule management.

Employer Challenges with Medical Data: An (Almost) Missed Opportunity

A large employer approached us to assist in managing infused specialty drugs. The client was concerned about overpaying for chronic complex therapies (eg, infliximab) that were being administered at the outpatient hospital setting. The first step of the analysis, of course, was to review its medical claims data to determine utilization patterns and the degree to which utilization was occurring in the outpatient hospital. To collect the data, the employer received a data extract directly from its medical carrier, according to detailed specifications provided by Walgreens.

Initially, the health plan data appeared acceptable. The requested fields were returned, and the integrity of the data seemed sufficient. For example, each claim's allowable amount was populated with the appropriate dollar values and diagnosis fields, and the provider fields were appropriately completed. On further inspection, however, we realized that the expected medical specialty per-member per-year cost was materially below our benchmarks. It was evident that claims from the outpatient hospital were substantially understated.

On isolating the issue, we asked the plan to re-run the data to include the suspected missing outpatient hospital claims. The health plan supplied a corrected file, which contained the exact same data as the first data set. Further discussion helped to convince the health plan that yet another data extract was necessary.

After several more attempts of unsuccessfully providing the outpatient hospital claims, the health plan concluded that the employer simply does not have much utilization occurring in the outpatient hospital. At one point, the health plan stated, "We've pulled every J code claim for this client, without any filters. I assure you that you have everything that we have."

Armed with the knowledge that nationally approximately 20% to 60% of medical specialty utilization occurs in the hospital outpatient department, and the fact that this client's utilization was well below our minimum expectation, we remained skeptical that we truly had a full data set. At that point, we recommended a 3-way call with Walgreens, the employer, and the health plan.

The health plan began the call affirming that it included all of the employer's medical claims to Walgreens. Walgreens then posed a question to the employer, "Do you have any benefit design restrictions that would prevent your employees from receiving infusions within an outpatient hospital setting?" The human resources representative for the employer immediately responded that a relative of his (who is also an employee of the company) receives infusion therapy at the local hospital. This patient was not represented in any of the data files produced by the payer. Needless to say, this caused the health plan to reconsider its position. A couple of weeks later, the health plan provided yet another data extract to Walgreens, but this time with outpatient hospital claims included.

Based on these new data, Walgreens demonstrated that 65% of the employer's medical specialty drugs were covered in the outpatient hospital, and that the employer could cut its infusion costs for non-chemotherapy specialty infusions by 57%; this was almost a missed opportunity, because of the payer's difficulty of producing an accurate utilization file.

The employer is currently implementing an SOC optimization program to transition patients from the outpatient setting to a more convenient and lower-cost SOC.

The significance of this story is 2-fold. First, without fully understanding what specific data to request, and what the data should look like, the opportunity for the employer never would have materialized. Second, once the appropriate data were received, the SOC strategy could be put into action, thereby allowing expanded and convenient access for patients and a substantial cost-reduction for the employer.

Table Cost Variance for Infusions at an ATS versus at a Hospital

Code	Drug	ATS rate, $	Outpatient hospital rate, $	Per-unit difference, %
J1745	Infliximab injection	63.4/unit	129.04/unit	103.27
		3134/claim	5790/claim	
J2323	Natalizumab injection	8.35/unit	13.30/unit	59.35
		2424/claim	3748/claim	

Note: average claim cost is dependent on the cost per unit and the units billed.

ATS indicates alternate treatment site.

Source: These data are based on Walgreens' internal analysis of 5,371,227 commercial managed care lives between January 2008 and December 2010.

Site-of-Care Optimization: Same Drug, Dose, and Prescriber, but Double the Cost?

Would you pay $50,000 for a car from one dealer that you could buy from a different dealer for $25,000? Would you pay $2000 for an economy seat on an airline when you could pay $1000 to fly first class?

As ridiculous as those questions appear, a parallel exists today in our healthcare delivery system. The cost of an infused drug could vary by more than 100%, depending on where patients go to receive their infusions. Considering that the average specialty infusion costs between $20,000 and $200,000 annually, doubling the cost to between $40,000 and $400,000 has a dramatic impact on the affordability and sustainability of continued access to these medications for payers and for patients.

SOC optimization programs are built around this variance in cost, allowing employers and health plans to direct patients to lower-cost SOCs. In most instances, patients are utilizing high-cost facilities, because they (and their physicians) are not aware of other options, or because the physician is incentivized to refer the patient to the hospital through some means, often because the physician is employed by the hospital.

Our current healthcare system is complex, and most patients seek infusion services wherever their physicians recommend, not realizing that drug costs are 110% higher at outpatient facilities compared with alternate treatment sites (ATSs), such as at-home infusion, infusion suites, and at physicians' offices.[4] The **Table** illustrates cost variance for 2 of the common nonchemotherapeutic specialty infusions at a hospital outpatient department versus an ATS.

Who can apply SOC strategies? The SOC strategy can be utilized by any entity that is responsible for paying a medical claim for infusion, including commercial health plans, government payers, self-insured employers, at-risk health systems, and at-risk independent practice associations. The size, location, and geographic layout of membership does not matter, as long as the partner or provider who is selected has the geographic coverage of services to match and has access to trained infusion nurses with specialty drug infusion expertise. As noted below, a major factor that determines the success of such an initiative is alignment of incentives through appropriate benefit design and shared-savings programs.

ASOCs and ATSs. The terms "alternate site of care" (ASOC) and "alternate treatment site" can be used interchangeably. ATSs or ASOCs are infusion sites outside of the traditional hospital (inpatient or outpatient) and skilled nursing facility settings. An ATS can be a patient's home, a physician's office, or an infusion suite.

The use of ATSs typically results in significant cost-savings for payers and for patients, and in an overall increased experience for the patients. Patients can receive acute and chronic infused medications in the ATS, and infusion suites are being built throughout the country, in locations such as within an infusion pharmacy, within a retail pharmacy, at an employer site, within a medical clinic, or as a stand-alone dedicated site. In addition, to meet payer needs and the acuity level of patients, these sites are now being staffed by registered nurses or by nurse practitioners. Services are focused on providing infusion therapy, but they also include other medical procedures, such as laboratory draws, injection training, simple wound care, and catheter care maintenance.

Keys to success. A critical component to the success of SOC optimization is ensuring appropriate benefit design at the payer level. Although SOC optimization offers a significant savings for a payer, appropriate benefit design ensures that the out-of-pocket expense for the patient is decreased (or even eliminated). If the member's benefit design does not provide a lower patient out-of-pocket cost at an ATS versus an outpatient department, it is very unlikely that the patient will agree to change the SOC. This dynamic can result in the payer continuing to pay more than double the amount for the service than is necessary.

Another component to success is alignment of incentives. Appropriate benefit design and/or a creative incentive program (eg, direct financial incentives to patients to move to a lower-cost SOC) align the incentives of the payer and the patient. However, this alignment must also occur between the payer and the provider to ensure optimal success. If alignment of incentives between the payer and the provider cannot be obtained, the probability is high that the higher-cost outpatient department will become the default location,

as was illustrated above. Emerging shared-savings programs and pay-for-performance reimbursement strategies can help to align payer and provider incentives.

It is important that the payer and the provider understand and agree to the measurement of success. Transparent data exchange and quarterly reporting play a critical role in making this possible. Without these elements in place, it is very possible that the true savings and value of SOC optimization may not be fully realized.

Options to Limit Physician Buy and Bill

Many physician specialties, such as oncology and rheumatology, provide in-office infusion for their patients. Receiving infusion in the physician's office is normally convenient for patients, a source of revenue for physicians, and often a cost-effective site of infusion for payers.

However, some payers worry that paying physicians tens of thousands of dollars annually to infuse medication in their offices may encourage overutilization, by influencing the physician to begin treating patients with therapy earlier or by keeping patients on therapy longer than is clinically appropriate. In addition, if a physician is financially incentivized to provide infusion therapy, the physician may be more likely to begin infusion therapy instead of to prescribe a more convenient, and often less costly, self-injected medication. Furthermore, rates paid to providers to infuse medications in the office, although often competitive, can vary considerably.

Therefore, some payers require that physicians' offices obtain medications that will be infused in their office from a contracted specialty pharmacy. This practice is also known as "white bagging." The pharmacy receives orders from physicians, fills the (patient-specific) medication, then mails the drug to the office before the patient's infusion or injection appointment. Some plans have been very successful with this strategy.[5] However, each payer will have different results, because of various underlying physicians' office fee schedules.[6]

Requiring physicians to make patients obtain infused or injected drugs for in-office administration from a specialty pharmacy is an individual decision that must be addressed by each health plan, based on its unique network design and fee schedules, member benefit design, local provider political influence, and specialty pharmacy pricing.

A plan can decide if a white bagging program would be an effective cost and utilization management program on completion of an analysis that accurately models how the cost of infused therapy would change if certain drugs were limited to only specialty pharmacy distribution. The current rate-setting methodology of the health plan's physician fee schedule is the primary driver for determining whether financial savings will occur if the drugs are blocked from buy and bill and are dispensed from a specialty pharmacy. Once the economic impact is understood, other strategic factors can be taken into consideration to make a fully informed decision.

Why an ATS Network Is Critical

Regardless of whether a plan restricts certain in-office drugs to a specialty pharmacy, it is critically important that a plan has an ATS network available to its members. Without an ATS network, infusions will, by default, be provided in hospital outpatient departments if the prescribing physician decides to no longer provide in-office infusions.

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With continuing price compressions and a plethora of high-cost medications in the drug pipeline, this poses a significant risk to plans: costs for the same drug will typically double if infused in a hospital setting versus at other settings. In addition, because health plans are increasingly purchasing physicians' practices,[7] we foresee infusion and injection at a physician's office decreasing over time, with a corresponding increase in hospital-based infusions, unless an ATS network exists.

Clinical and Formulary Management

Health plans have many opportunities to introduce clinical and utilization programs to manage appropriate utilization in the medical benefit—so many, in fact, that it is beyond the scope of this article to detail them all.

Having a full understanding of clinical opportunities will lead to programs that can manage utilization trends within the medical benefit. For example, the effectiveness of a payer's current prior authorization (PA) criteria can be evaluated, additional PA and formulary opportunities can be explored, and programs focused on converting patients from infused drugs to self-administered drugs (injected or oral) can be evaluated once a payer understands the utilization patterns within his or her medical benefit.

Fee Schedule Management

One of the most straightforward ways to manage drug-related medical costs for a payer is to maintain a

competitive and continually maintained fee schedule that determines how much a provider is paid for a drug and its administration. However, a payer must be cautious when adjusting fee schedules. Remember that ATSs and outpatient hospital facilities are usually contracted and managed separately. If fee schedules to the ATS network are reduced to a point where providers feel the level of reimbursement does not adequately compensate them for the drug, the ATS will likely choose to no longer provide infusion services.

The prescribing physician will then either attempt to switch the patient to a self-administered drug, or more likely (because there are only a few infused products with a self-administered equivalent product), will refer the patient to a nearby outpatient hospital to continue the infusion treatment. This will result in a significant cost increase to the payer for that infusion, thereby more than eliminating the expected cost-savings the payer would otherwise have predicted from the lower fee schedule.

An MBM analysis should be able to provide payers a perspective on industry benchmarks and how their fee schedules are performing relative to their industry peers. In addition to enabling payers to see if they are in line with what other payers are reimbursing for certain drugs, an analysis showing that payers have an extremely deep ATS fee schedule (eg, average sales price +6) and an unusual amount of hospital outpatient utilization may indicate that more research may help to determine if cause and effect exists, perhaps even leading payers to evaluate if increasing the ATS fee schedule would decrease net infusion costs resulting from lowering hospital outpatient utilization.

The Ultimate Successful MBM Strategy

Payers will be well on their way to effectively managing medical specialty drug costs if they:

- Implement an ATS network (including infusion suites and home infusion options) to mitigate hospital outpatient referrals for specialty infusion
- Maximize the use of lower-cost ATSs for infusion through appropriate benefit design and provider incentives
- Align financial incentives with the infusion partner—through a shared-savings strategy and/or a preferred provider contract
- Maintain fair and competitive fee schedules across all SOCs, ensuring physicians' offices, home infusion providers, and infusion suites are incented to provide infusion services
- Manage clinical appropriateness through PA programs and/or clinical pathways
- Maintain fee schedules that do not encourage the use of high-cost products when lower-cost therapeutically equivalent options exist
- Have access to utilization reporting that tracks savings and trends within the medical benefit.

Conclusion

Managing the medical pharmacy trend is a complex task, and many solutions are available from various vendors to help payers manage medical pharmacy utilization. Drug utilization within the medical benefit is increasingly becoming better understood and managed, but not yet to the extent of pharmacy utilization.

Before committing to an MBM strategy, a plan should first feel comfortable with understanding its medical pharmacy trend and utilization patterns within each place of service and type of service (eg, chemotherapy or nonchemotherapy). A payer has to understand what its top drugs are, which physician specialties are driving the utilization, and what SOC its benefit design currently encourages patients to utilize.

A payer should ask any potential consulting pharmacy partner to see examples of its MBM reporting, and then ask what solutions that partner can provide. Does the vendor have a strategy and implementation plan for each area of opportunity, or will multiple vendors be required? If multiple vendors are needed, can the vendors work collaboratively to provide a uniform solution to the payer? ■

Author Disclosure Statement

Mr Einodshofer and Dr Duren are employees and stockholders of Walgreens.

References

1. Einodshofer M, Kansler S. Cost management through care management: a perspective on choosing the right specialty pharmacy partner. *Am Health Drug Benefits*. 2012;5:301-304.

2. Express Scripts. 2011 Drug Trend Report. www.expressscripts.com/research/research/dtr/archive/2012/dtrFinal.pdf. Accessed September 21, 2012.

3. CVS Caremark to offer medical benefit drug management services to clients. April 14, 2011. http://info.cvscaremark.com/newsroom/press-releases/cvs-caremark-offer-medical-benefit-drug-management-services-clients. Accessed September 21, 2012.

4. Einodshofer M, Frear RS, Gomberg JB. 2012 Health Meeting Session 89 TS: Specialty Drugs. June 13-15, 2012. www.soa.org/files/pd/health/2012-new-orleans-health-89.pdf. Accessed September 21, 2012.

5. Baldini CG, Culley EJ. Estimated cost savings associated with the transfer of office-administered specialty pharmaceuticals to a specialty pharmacy provider in a medical injectable drug program. *J Manag Care Pharm*. 2011;17:51-59.

6. ICORE Healthcare. Medical Injectables and Oncology Trend Report. 2010. www.magellanhealth.com/media/281539/icore_trend_report_1-20-11.pdf. Accessed September 22, 2012.

7. Elliott VS. Increase in physician practice mergers and acquisitions expected to continue. August 14, 2012. www.ama-assn.org/amednews/2012/08/13/bisd0814.htm. Accessed September 21, 2012.